

IN THE SPECIFICATION

Please replace the paragraph on Page 1, beginning on line 24, with the following:

a1 Individual's suffering from pulmonary edema, i.e., the effusion of ~~serious~~ serous fluid into the lungs, and certain other respiratory ailments are generally treated by forcing breathable gas, normally oxygen (O₂) into the lungs and maintaining the pressure within the lungs at a level, e.g., 1 to 20 centimeters of water above atmospheric. The O₂ can be supplied directly to the lungs through an endotracheal tube, one end of which is inserted into the lungs through the individual's mouth, i.e., intubation. The invasive technique of intubation requires considerable skill and can cause serious injury to the patient. Also, the recovery time of intubated patients may be considerable.

Please replace the paragraph on Page 7, beginning on line 23, and ending on page 8, line 5, with the following:

a2 Referring now to the drawings, and particularly to the system schematic of the invention shown in Fig. 1, a demand oxygen regulator 10 is powered by a pressurized O₂ source 11 through an inlet port 12. An adjustable back pressure regulator 14 receives pressurized O₂ on conduit or line 15 through a flow restrictor 16. A pressure gauge 18 provides a measure of the pressure within the outlet 22 of a demand oxygen regulator 10. O₂ at the desired pressure, is supplied from the demand oxygen regulator outlet 22, to a mask 20, via an inlet ~~26a~~ 58a of a balanced inhalation/exhalation patient valve ~~26~~ 58 attached to or incorporated into the mask, and a conventional hose or tube 25. The inlet ~~26a~~ 58a is hereinafter sometimes referred to as the breathing appliance inlet.

Please replace the paragraph on Page 8, beginning on line 6, with the following:

Low flow O₂ is also supplied to a nebulizer 26 from a nebulizer outlet 28, and a nebulizer shut off valve 30 (incorporated in the pressure regulator as will be described in more detail) and line 27. The output of the nebulizer is combined with the O₂ delivered to the patient's mask through the tube 25 29 in a conventional manner.

Please replace the paragraph on Page 8, beginning on line 20, with the following:

a4 Referring now to Fig. 4 the demand O₂ regulator 10 includes a demand valve 40, a maximum pressure relief valve 38 and an anti-suffocation valve 39. The valves 38 and 39 are mounted in a housing 42 which is secured to the demand valve housing by bolts, for example. The upstream interior section of the housing 41 42 forms the outlet port 46 for the demand valve, as will be discussed in more detail in connection with Figs. 7 and 8.

Please replace the paragraph on Page 9, beginning on line 5, with the following:

a5 Referring now to Fig. 5 the back pressure regulator valve 14 is a conventional poppet valve with a top housing section 14a, a lower housing section 14b, an inlet 14c connected to the pressurized source via restrictor 16 (Fig. 3), an atmospheric outlet port 14d, and a valve plate 14e which is biased against seat 14f by spring 14g. An axially moveable plunger 14h responds to the rotation of knob 14i to adjust the compressive force applied by the spring to the valve plate 14e which in turn restricts the flow in line 15 from the O₂ source 11 to adjust the back pressure at inlet 14c, e.g., 1 to 20 cm H₂O to establish the desired reference pressure in line 15a 15 to the demand valve as will be described in connection with Figs. 7 and 8.

Please replace the paragraph on Page 9, beginning on line 19, with the following:

a6 The nebulizer 26, as shown in Fig. 6, includes a container 26a for liquid medication 26b.

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Pressurized O₂ leaving nozzle 26c educts vaporized medication into stream 26d which enters the tube ~~25~~ 29 adjacent the face mask during the inhalation phase of the patient's breathing cycle.

Please replace the paragraph on Page 10, beginning on line 17, with the following:

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A passageway 36c connects the upper chamber 52a, the pilot valve orifice 54f and inner chamber 30a to the pressurized source via a flow restrictor 36d. Passageway ~~46e~~ 36e connects the lower chamber 54b of valve 54 to an outlet chamber 46c of the demand valve, which chamber extends above the outlet port and circumferentially around a nozzle 46b.

Please replace the paragraph on Page 12, beginning on line 16, with the following:

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The operation of the nebulizer valve 30 may best be understood by reference to Figs. 10-12. The inlet pressure, e.g., 50 psi, is applied to both chambers 30a and 30b of the third valve 30 in the static condition, i.e., pilot valve 54f and main valve 52 are closed. In the absence of O₂ flow through the main valve 52, e.g., exhalation mode, the diaphragm 30c closes the nebulizer outlet 50 due to the unequal areas of the diaphragm exposed to the opposing chambers. When the pilot and main valves open, at the initiation of inhalation, the pressure (P1) in passageway 36c decreases immediately, as explained earlier, allowing the diaphragm 30c to open the nebulizer valve. This allows O₂ to flow through restrictor 30d (Fig. 10), into the nebulizer outlet 50, through restrictor 54 to the nebulizer nozzle 26c.

Please replace the paragraph beginning on page 13, line 19, with the following:

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In the exhalation mode the pressure P3 (Fig. 12) in line ~~58~~ 60 and chamber 56a is low and the valve 56 is open connecting the line 15 and reference chamber to the inlets of both pressure regulators. As a result the reference pressure is dictated by the pressure regulator having the lowest pressure setting, i.e., valve 14'. In the inhalation mode, with the main valve open, the pressure P3

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in line ~~58~~ 60 rises to force diaphragm 56c against the seat surrounding the outlet 56e thereby connecting only the inlet of the regulator 14 to the line 15 and the reference chamber. In this mode the reference pressure is set by the regulator 14.

Please replace the paragraph beginning on page 14 at line 6 with the following:

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An alternative embodiment of a bi-level system is illustrated in Figs. 15 and 16. This system functions in similar manner with one of the pressure regulators, i.e., regulator 55 being preadjusted at the factory to connect its input 55a to atmosphere via output 55b at a selected pressure, e.g., 10 cm H₂O. A selector diaphragm valve 57 connects the outlet 14d of pressure regulator 14 to atmosphere via line 59a, inlet port 57a, and outlet port 57b during the exhalation mode as is illustrated in Fig. 15. During the inhalation mode (Fig. 16) the rise in pressure in line ~~58~~ 60 (P3, Fig. 12) transmitted through inlet orifice 57c causes diaphragm 57d to close outlet 57b, connecting the outlet of pressure regulator 14 to the inlet 55a of pressure regulator 55. Thus, the inhalation pressure will always be a fixed pressure (e.g., 10 cm H₂O) above the exhalation pressure as set by the manually adjustable pressure regulator 14.

Please replace the paragraph beginning on page 14 at line 29 through page 15 line 28 with the following:

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Figs. 17 and 18 illustrate a cross-sectional schematic view of an improved patient valve arrangement 58 for use with or incorporation into a patient's face mask in accordance with this invention. The patient valve 58 comprises an inlet passage 58a terminating in an inhalation check valve 58b that acts to permit flow from the inlet 58a to an inlet/outlet chamber 58c which in turn is adapted to be placed in fluid communication with the patient's airway via a face mask etc. A passage 58d conducts gas (O₂) from the inlet to a diaphragm chamber 58e. This chamber is formed

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by the upper surface of diaphragm 58f secured at its periphery to the inner wall of valve housing 58j, the upper top central surface 58g of a circular valve member 58h and the interior of an upper section 58i of the generally cylindrically shaped valve housing 58j as illustrated. The valve member 58h is secured to and suspended by the radially inner portion of the diaphragm. This chamber 58e acts to provide pneumatic damping and pressure balance to the operation of valve member 58h. When the patient exhales, the pressure in the inlet/outlet chamber 58c rises above the pressure in the inlet 58a. This causes check valve 58b to close, allowing diaphragm 58f and valve member 58h to move upwardly lifting the valve member off of its annular seat ~~58k~~ 58m formed at the upper (terminal) end of the inlet/outlet chamber 56c. Flow is then directed through an exhaust casing ~~58l~~ 58k which surrounds the valve seat and thence to exhaust port ~~58m~~ 58n and to atmosphere via passage ~~58n~~ 58o. The exhaust port, formed in exhaust casing 58l, which is rotatable through an angle of about 300° with respect to the valve housing 58j allows the patient's expired air to be directed as desired.

Please replace the paragraph beginning at page 15, line 29, with the following:

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An important design feature of the valve is the balancing of the effective areas of the diaphragm 58f (and upper surface 58g of the valve member) and the valve seat area ~~58k~~ 58m. The effective area of the diaphragm has a diameter d1 and the median diameter of the valve seat is d2. These two diameters are preferably about equal. This feature allows the exhalation pressure to be maintained at a level almost equal to the inhalation pressure in inlet 58a, regardless of the positive pressure level.
